

the frangible seal **1069** divides the housing **1010** into two isolated receptacles, an upper receptacle **1020** and a lower receptacle **1024**.

[**0153**] The plunger **1050** comprises a handle **1052**, a shaft **1051**, and a tip **1090**. The handle **1052** can be constructed as described above and may comprise an optional rim **1054** that engages the housing **1010** to prevent the plunger **1050** from being inserted too far into the housing **1010**. The handle **1052** can be coupled to the shaft **1051** via a threaded fit or by other coupling means (e.g., press-fit, adhesive). The tip **1090** may be fabricated using processes and materials described for other tip embodiments described herein. The tip **1090** may comprise one or more guides **1083**. The guides are dimensioned to loosely fit within the interior of the housing **1010** and function to reduce lateral movement of the tip **1090** as the tip **1090** moves longitudinally through the housing **1010**.

[**0154**] The tip **1090** further comprises a scraper **1086**, which is held in a fixed position on the tip **1090**. In the illustrated embodiment, the scraper **1086** is held in a fixed position by retaining member **1087**. The retaining member **1087** can be molded or machined as part of the tip **1090** or it can comprise a bracket or plurality of brackets coupled to the tip **1090**. Alternatively, the scraper **1086** may be directly coupled (e.g., adhesively coupled) to the tip **1090**.

[**0155**] The scraper **1086** is disc-shaped and is dimensioned to form a relatively tight fit inside the housing **1010**. In some embodiments, the scraper can comprise an O-ring. The scraper **1086** should substantially maintain its shape when immersed in an aqueous liquid. Although the scraper should be dimensioned to form a relatively tight fit inside the housing, the scraper should be relatively flexible to permit fluid to flow around its edge as the plunger is pushed through a liquid sample in the housing **1010**. Suitable materials for fabricating the scraper **1086** include, for example polyurethane rubber.

[**0156**] In use, a liquid sample **1040** and a cell concentration agent **1030** are contacted in the housing **1010** of the device, as shown in FIG. **10B**. The plunger **1050** is inserted into the housing **1010** and the tip **1090** of the plunger **1050** is urged toward the bottom of the housing **1010**. As the tip **1090** passes through the liquid sample **1040**, the cell concentration agent **1030** is urged toward the bottom of the housing **1010** by the scraper **1086**, while the liquid sample **1040** flows around the edge of the scraper **1086**. Advantageously, this device allows the user to collect and concentrate the cell concentration agent **1030** in a substantially shorter period of time than possible if the cell concentration agent **1030** is allowed to settle by gravity force to the bottom of the housing **1010**. Furthermore, the flexible scraper facilitates collecting a portion of cell concentration agent **1030** that might otherwise adhere to the walls of the housing. Thus, the inventive device **1000** increases the recovery of the cell concentration agent and, thereby, increases the sensitivity of a method that uses a cell concentration agent to concentrate microorganisms.

[**0157**] It should be recognized that, in a sample preparation and detection device in which the cell concentration agent comprises ferromagnetic materials (e.g., particles), that a magnet or an electromagnet can be positioned adjacent the device to draw the particles (and microorganisms coupled thereto) to a desired location for collecting the particles and/or transferring them to another receptacle. In some embodiments, the magnet can be positioned adjacent the device (e.g., adjacent the bottom of the device) after a sufficient period of time to allow for the cell concentration agent to couple substantially all of the microorganisms in the liquid sample.

Methods of Detecting Biological Analytes from Live Cells:

[**0158**] Methods of the present disclosure include methods for the detection of biological analytes that are released from live cells including, for example, live microorganisms, after exposure to an effective amount of cell extractant.

[**0159**] Methods of the present disclosure include the formation of a liquid mixture comprising a sample suspected of containing live cells and a hydrogel comprising a cell extractant. Methods of the present disclosure further include detecting a biological analyte. Detecting a biological analyte can further comprise quantitating the amount of biological analyte in the sample.

[**0160**] In one aspect, the present disclosure provides a method of detecting cells in a sample. The method comprises providing a cell concentration agent, a hydrogel comprising a cell extractant and a liquid sample suspected of containing cells. Suitable cell concentration agents are described in U.S. Patent Application No. 60/977,180 filed on Oct. 3, 2007, and entitled "MICROORGANISM CONCENTRATION PROCESS", which is incorporated herein by reference in its entirety.

[**0161**] The method further comprises contacting the liquid sample and the cell concentration agent for a period of time. The cell concentration agent can comprise particles, fibers, a matrix (e.g., a fibrous matrix) comprising particles, or any combination of two or more of the foregoing. The cell concentration agent can be suspended in the liquid sample during the contact period. The suspension can be placed into a vessel, such as a tube, a flask, a beaker, or any of the detection devices described herein. In certain preferred embodiments, the liquid sample is mixed with the cell concentration agent for a period of time by, for example, stirring, vortexing, or vibrating the suspension. While the cell concentration agent is contacted with the liquid sample, cells from the liquid sample are coupled to the cell concentration agent.

[**0162**] The method further comprises isolating the cell concentration agent from at least a portion of the liquid sample. During this process, the cell concentration agent may be concentrated in a smaller volume than the original liquid sample. The cell concentration agent can be isolated from at least a portion of the liquid sample by a variety of means. For example, if the cell concentration agent has a higher specific gravity than the liquid sample, the cell concentration agent can settle to the bottom of the suspension. At least a portion of the liquid sample can be removed (e.g., by pipetting or decanting). Alternatively, or additionally, at least a portion of the liquid sample can be removed by centrifugation or filtration.

[**0163**] A filter can be described by its pore size (for example by its bubble point pore size). The bubble point pore size of a filter is generally the average of the largest size of the pores of the filter. In some embodiments, the filter can have an average pore size that is less than the average size of the cell concentration agent. The ability to utilize filters having these relatively large pore sizes offers significant advantages to methods as disclosed herein when compared with other methods for separating microorganisms from samples, such as water samples.

[**0164**] In an embodiment, the filter can have an average pore size that is at least about 1 micrometer ( $\mu\text{m}$ ) or larger. In an embodiment, the filter can have an average pore size that is at least about 1.5  $\mu\text{m}$  or larger. In an embodiment, the filter can have an average pore size that is at least about 5  $\mu\text{m}$  or larger. In an embodiment, the filter can have an average pore size that